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Purpose of this guide

If you want to make changes to an already approved human ethics protocol, you need to lodge a variation request with the approving review body.

Variations for a project that was approved by a University ethics review panel can be lodged using the 'Variation' application form available in [RIMS](#).

Common variation requests include:

- changes to the participant group
- changes to the research team, such as the addition or removal of students or assistants who will be involved in conducting the research
- changes to procedures, such as the number or timing of tests or tasks
- changes to data collection sites.

This guide provides advice on preparing a 'Variation' application to an already-existing human ethics protocol

One eForm, two application types

In February 2022, we introduced a new eForm that researchers can use for 'Initial / New Project' applications **and** 'Variation' applications. Previously, 'Variation' applications were made using a separate, stand-alone form.

Now when a 'Variation' application is created, RIMS produces a new version of the original approved protocol, which you update to reflect the changes you want to make to your research project.

Once a 'Variation' application is approved, the eForm is then 'locked down' and will stay this way until another variation is submitted and approved. Because of this variation model, **only one variation can be submitted at a time**.

Important advice for protocols developed on the old eForm

If you need to lodge a 'Variation' application for an research project created on the old eForm (i.e, before February 2022), you **must** contact the Human Research Ethics team at human-ethics@newcastle.edu.au to request that data from your original application is migrated to the new eForm.

A member of the team will contact you once the migration is complete so you can review the protocol for accuracy. They will also create a 'Variation' application in RIMS for you, so you can begin preparing your submission.

If you are looking to create a 'Variation' application on a **protocol that has been approved on the current eForm**, you do not need to follow these steps. You can create the variation yourself as outlined from page 5.

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Creating a 'Variation' application to an existing protocol

Accessing a migrated Variation application

If the Human Research Ethics team has advised you that the migration of data from your old eForm to the new one is complete, you can start developing your 'Variation' application.

Accessing your protocol

If you are listed as the Chief Investigator on the protocol, use the **Locate My Records** option from the top menu bar of your RIMS screen to access the approved protocol.

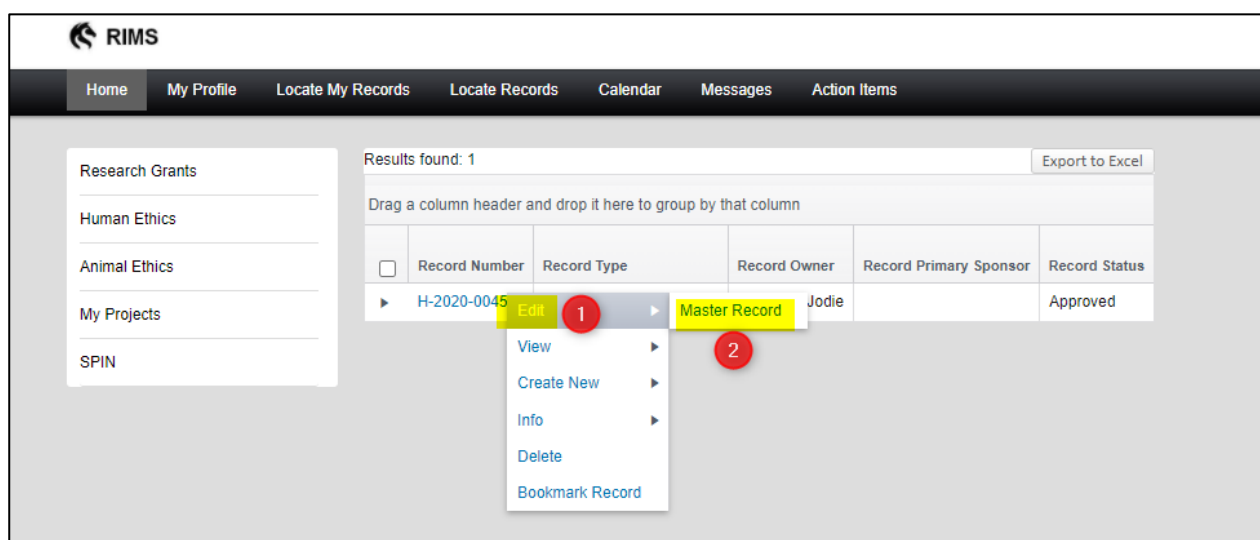
For all other researchers listed on the eForm for the ethics protocol, please use the **Quick Find** search to access.

Please refer to the *RIMS User Guide – Getting Started and Locating Records* for more advice about how to access the record you wish to work on.

Accessing the Variation application

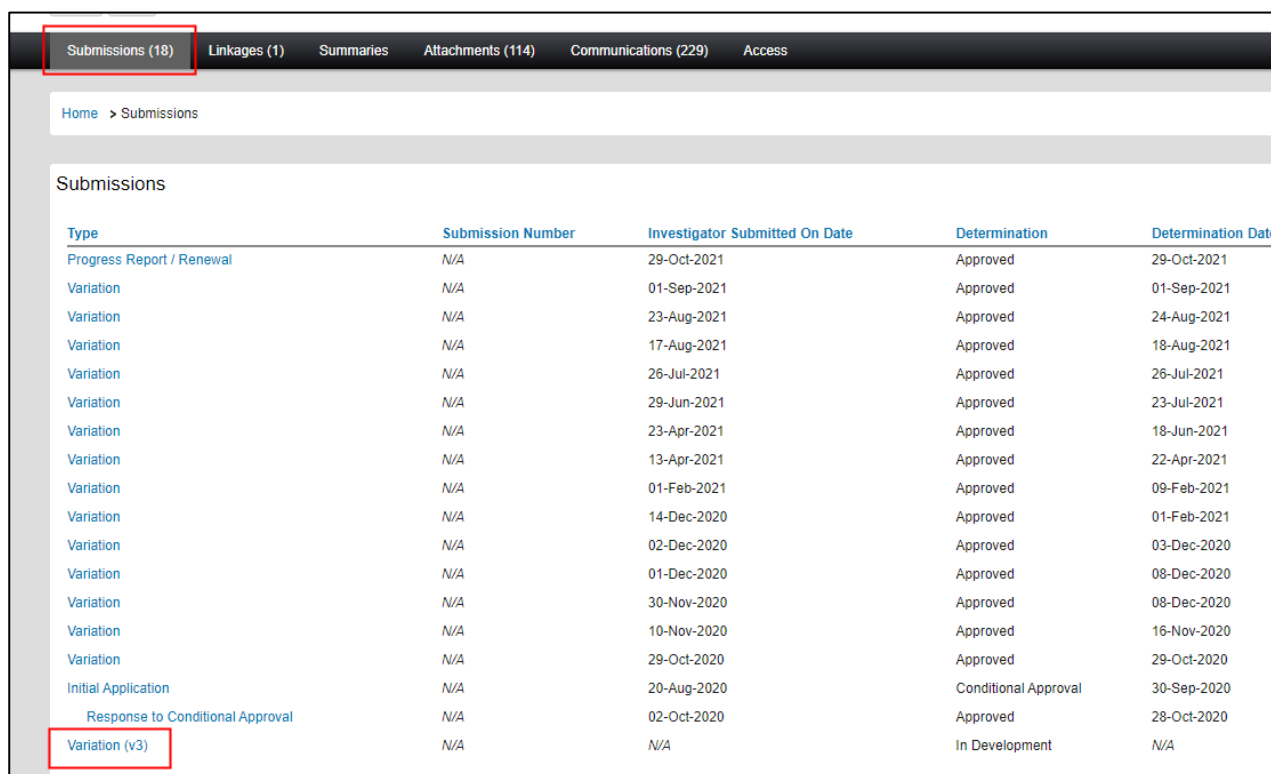
Once you've located the desired record, select the **Edit** option and then **Master Record**, as shown in Figure 1.

Figure 1



From there, navigate to the **Submissions** tab, as shown in Figure 2.

Figure 2



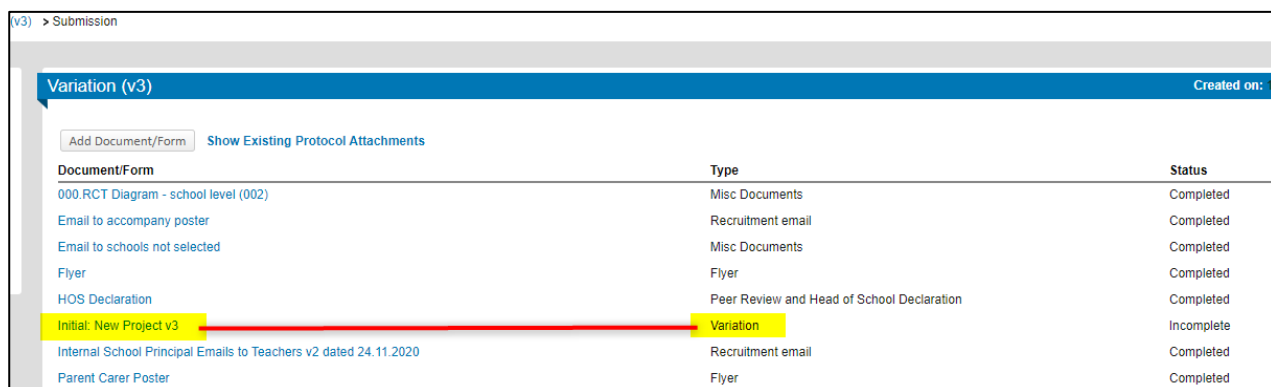
| Type | Submission Number | Investigator | Submitted On Date | Determination | Determination Date |
|----------------------------------|-------------------|--------------|-------------------|----------------------|--------------------|
| Progress Report / Renewal | N/A | | 29-Oct-2021 | Approved | 29-Oct-2021 |
| Variation | N/A | | 01-Sep-2021 | Approved | 01-Sep-2021 |
| Variation | N/A | | 23-Aug-2021 | Approved | 24-Aug-2021 |
| Variation | N/A | | 17-Aug-2021 | Approved | 18-Aug-2021 |
| Variation | N/A | | 26-Jul-2021 | Approved | 26-Jul-2021 |
| Variation | N/A | | 29-Jun-2021 | Approved | 23-Jul-2021 |
| Variation | N/A | | 23-Apr-2021 | Approved | 18-Jun-2021 |
| Variation | N/A | | 13-Apr-2021 | Approved | 22-Apr-2021 |
| Variation | N/A | | 01-Feb-2021 | Approved | 09-Feb-2021 |
| Variation | N/A | | 14-Dec-2020 | Approved | 01-Feb-2021 |
| Variation | N/A | | 02-Dec-2020 | Approved | 03-Dec-2020 |
| Variation | N/A | | 01-Dec-2020 | Approved | 08-Dec-2020 |
| Variation | N/A | | 30-Nov-2020 | Approved | 08-Dec-2020 |
| Variation | N/A | | 10-Nov-2020 | Approved | 16-Nov-2020 |
| Variation | N/A | | 29-Oct-2020 | Approved | 29-Oct-2020 |
| Initial Application | N/A | | 20-Aug-2020 | Conditional Approval | 30-Sep-2020 |
| Response to Conditional Approval | N/A | | 02-Oct-2020 | Approved | 28-Oct-2020 |
| Variation (v3) | N/A | | N/A | In Development | N/A |

As part of the data migration process described earlier, the Human Research Ethics Team would have created a 'Variation' application for you. It will be called 'Variation (v3)' and can be found at the bottom of your **Submissions** summary as shown in Figure 2.

Click on '**Variation (v3)**' to open the file.

Next, select the **Variation** option from the list of documents associated with your protocol, as shown in Figure 3.

Figure 3



| Document/Form | Type | Status |
|--|--|------------|
| 000.RCT Diagram - school level (002) | Misc Documents | Completed |
| Email to accompany poster | Recruitment email | Completed |
| Email to schools not selected | Misc Documents | Completed |
| Flyer | Flyer | Completed |
| HOS Declaration | Peer Review and Head of School Declaration | Completed |
| Initial: New Project v3 | Variation | Incomplete |
| Internal School Principal Emails to Teachers v2 dated 24.11.2020 | Recruitment email | Completed |
| Parent Carer Poster | Flyer | Completed |

Creating variation applications to protocols on the new eForm

If your 'Initial / New Project' application was approved on the new eForm (from 7 March 2022 onwards) – or if you want to prepare a variation on an older protocol which the Human Research Ethics team has already migrated for you – you can create a 'Variation' application yourself.

Accessing your existing protocol

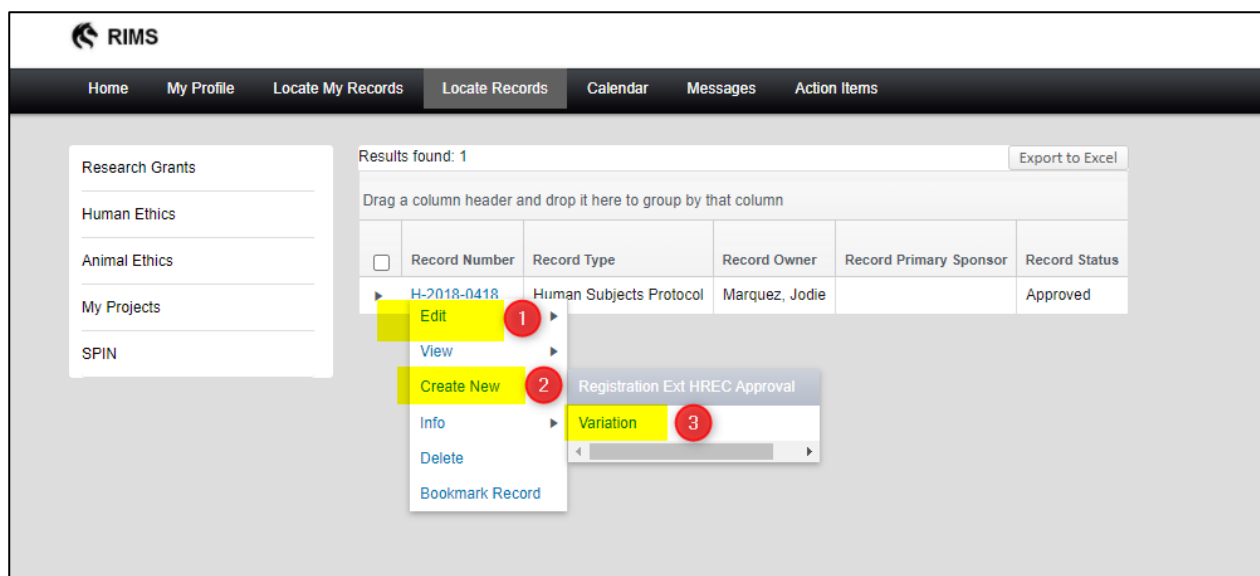
If you are listed as the Chief Investigator on the protocol, use the **Locate My Records** option from the top menu bar of your RIMS screen to access the approved protocol.

For all other researchers listed on the eForm for the ethics protocol, please use the **Quick Find** search to access.

Please refer to the *RIMS User Guide – Getting Started and Locating Records* for more advice about how to access the record you wish to work on.

Once you've located the record, select the **Edit** option, **Create New** and then **Variation** as shown in Figure 4.

Figure 4



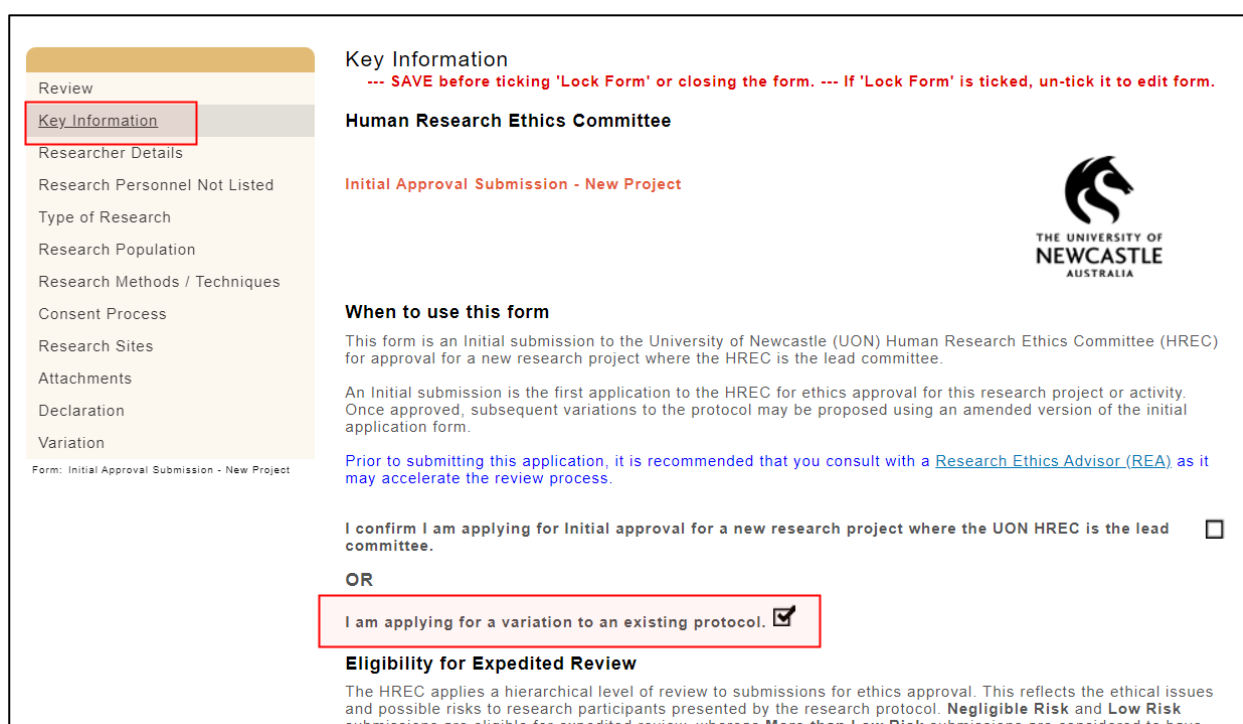
Each variation is a 'copy' of your current protocol approval, so your Variation submission will now open directly on your approved eForm for you to continue preparing.

Creating a 'Variation' application

Once you open the 'Variation' application, go to the **Key Information** tab in the left menu bar, as shown in Figure 5.

From here, you'll need to make sure the **'I am applying for a variation to an existing protocol'** option is selected. If you have already had a variation approved on this eForm you will not need to complete this step as it will already have been ticked.

Figure 5



The screenshot shows the 'Key Information' tab selected in the left-hand menu. The main content area displays the following information:

- Key Information**
--- SAVE before ticking 'Lock Form' or closing the form. --- If 'Lock Form' is ticked, un-tick it to edit form.
- Human Research Ethics Committee**
- Initial Approval Submission - New Project**
- When to use this form**
This form is an Initial submission to the University of Newcastle (UON) Human Research Ethics Committee (HREC) for approval for a new research project where the HREC is the lead committee.
An Initial submission is the first application to the HREC for ethics approval for this research project or activity. Once approved, subsequent variations to the protocol may be proposed using an amended version of the initial application form.
Prior to submitting this application, it is recommended that you consult with a [Research Ethics Advisor \(REA\)](#) as it may accelerate the review process.
- I confirm I am applying for initial approval for a new research project where the UON HREC is the lead committee.**
- OR**
- I am applying for a variation to an existing protocol.**
- Eligibility for Expedited Review**
The HREC applies a hierarchical level of review to submissions for ethics approval. This reflects the ethical issues and possible risks to research participants presented by the research protocol. **Negligible Risk** and **Low Risk** submissions are eligible for expedited review, whereas **More than Low Risk** submissions are considered to have

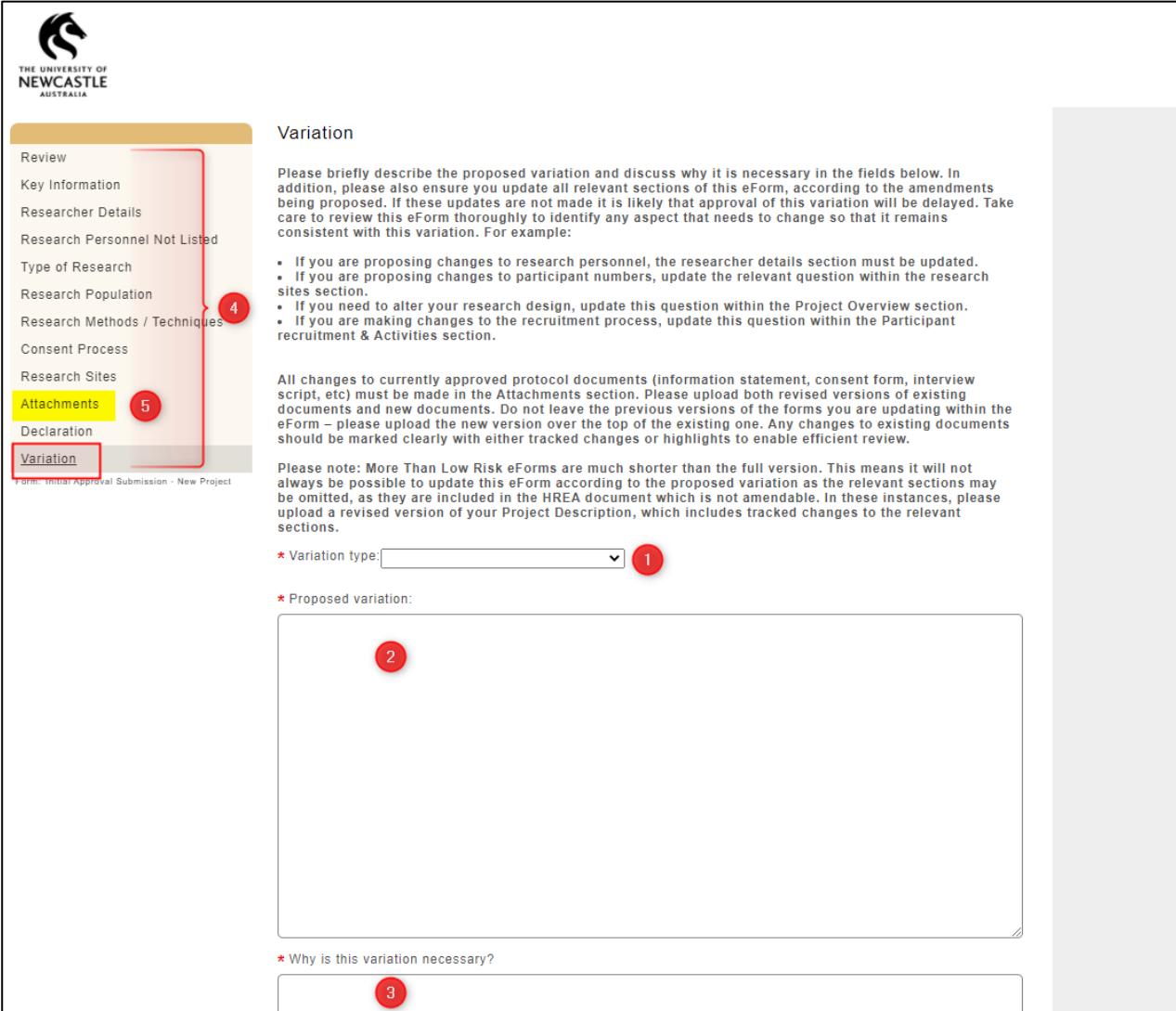
If your Variation is on a migrated eForm, please ensure you now review the content within your application eForm. As part of the migration process, the Human Research Ethics team will have updated your protocol to reflect any variations that have been previously approved. As such, this version should be completely current.

Preparing your Variation submission

To start preparing your 'Variation' application, go to the **Variation** tab at the bottom of the menu on the left side of the RIMS screen.

From here, you will need to complete several fields, as shown in Figure 6:

Figure 6



Variation

Please briefly describe the proposed variation and discuss why it is necessary in the fields below. In addition, please also ensure you update all relevant sections of this eForm, according to the amendments being proposed. If these updates are not made it is likely that approval of this variation will be delayed. Take care to review this eForm thoroughly to identify any aspect that needs to change so that it remains consistent with this variation. For example:

- If you are proposing changes to research personnel, the researcher details section must be updated.
- If you are proposing changes to participant numbers, update the relevant question within the research sites section.
- If you need to alter your research design, update this question within the Project Overview section.
- If you are making changes to the recruitment process, update this question within the Participant recruitment & Activities section.

All changes to currently approved protocol documents (information statement, consent form, interview script, etc) must be made in the Attachments section. Please upload both revised versions of existing documents and new documents. Do not leave the previous versions of the forms you are updating within the eForm – please upload the new version over the top of the existing one. Any changes to existing documents should be marked clearly with either tracked changes or highlights to enable efficient review.

Please note: More Than Low Risk eForms are much shorter than the full version. This means it will not always be possible to update this eForm according to the proposed variation as the relevant sections may be omitted, as they are included in the HREA document which is not amendable. In these instances, please upload a revised version of your Project Description, which includes tracked changes to the relevant sections.

* Variation type: 1

* Proposed variation:

2

* Why is this variation necessary?

3

4

5

1. **Variation type:** Indicate what the proposed variation involves (personnel only; protocol only; or personnel and protocol).
2. **Describe the proposed variation:** Provide a brief description of what the variation(s) consists of. This should specify the elements you propose to change, remove, or add to the approved protocol.
3. **Describe why the variation is necessary.** The information included here should give reviewers insight into the rationale for the proposed changes.
4. **Determine what other sections of the eForm need to be updated to support your proposed variation request.** For example:
 - If you want to add additional research sites to your study, you will need to update the **Research Sites** section of the eForm.

- If you are changing an element of your recruitment, you'll need to update the **Participant Recruitment & Activities** section.

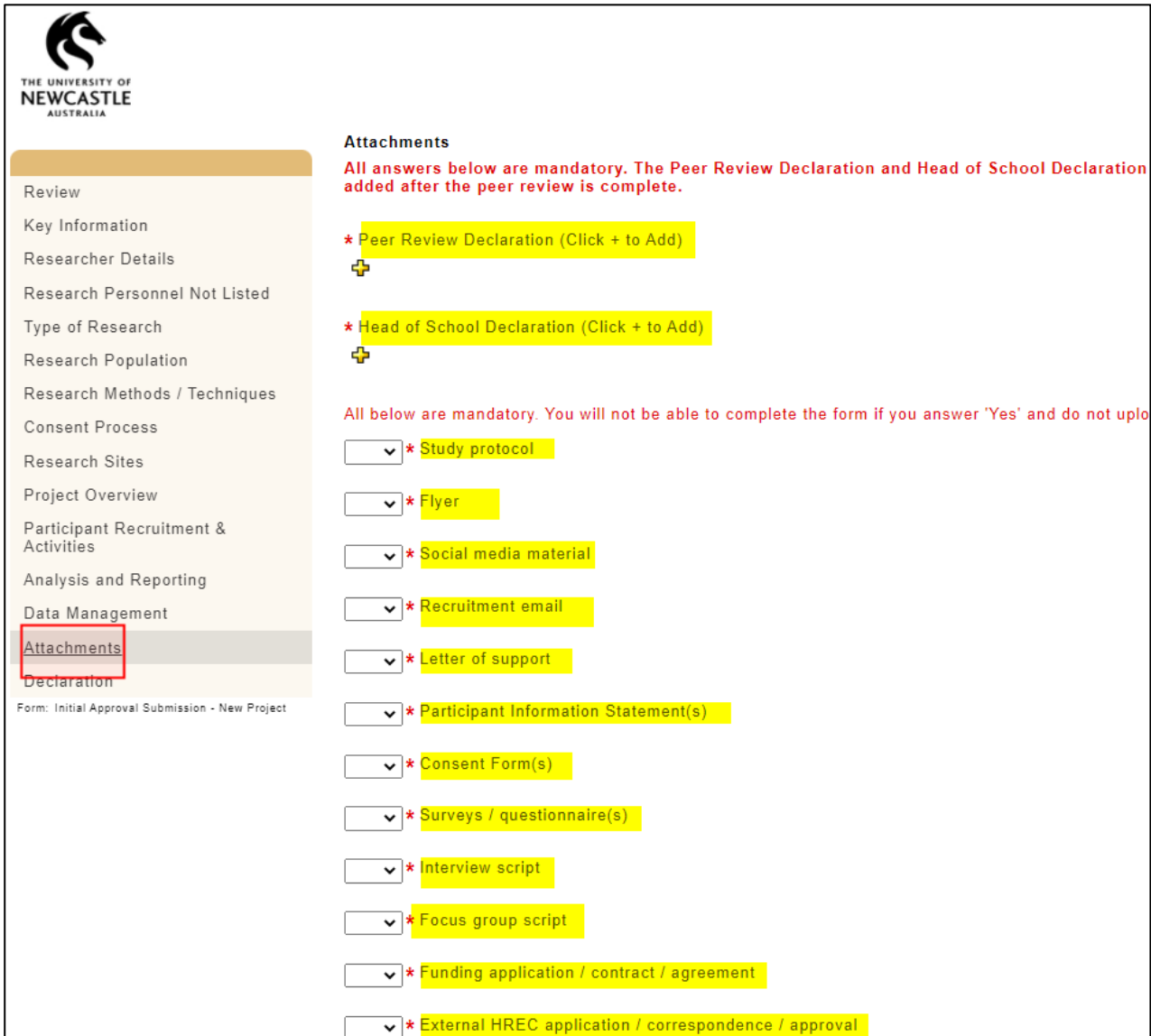
Because the new eForm is used for 'Initial / New Project' applications *and* 'Variation' applications, it becomes the single source of truth for your ethics protocol, and all sections need to reflect the current state of your research project.

5. In the **Attachments** tab, you can upload new documents or revised versions of existing documents related to proposed variation. The next sections provide advice on how to do this in the new eForm.

Attaching supplementary documents

All attachments can be uploaded within the **Attachments** tab as shown in Figure 7.

Figure 7



Attachments

All answers below are mandatory. The Peer Review Declaration and Head of School Declaration added after the peer review is complete.

- * Peer Review Declaration (Click + to Add)
- +
- * Head of School Declaration (Click + to Add)
- +

All below are mandatory. You will not be able to complete the form if you answer 'Yes' and do not upload.

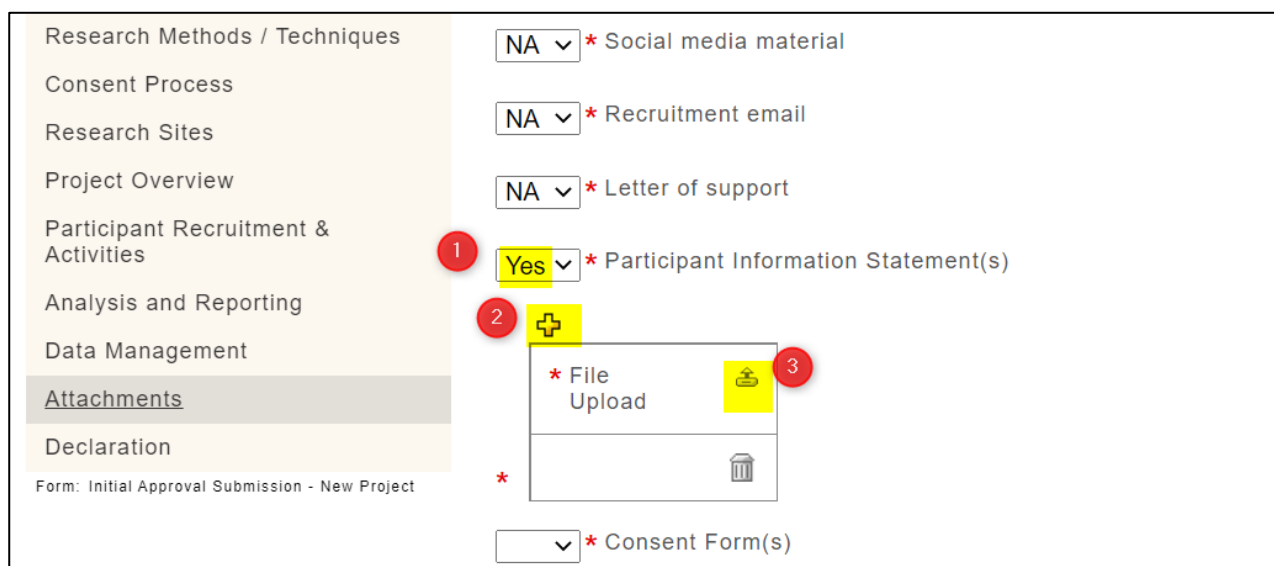
- * Study protocol
- * Flyer
- * Social media material
- * Recruitment email
- * Letter of support
- * Participant Information Statement(s)
- * Consent Form(s)
- * Surveys / questionnaire(s)
- * Interview script
- * Focus group script
- * Funding application / contract / agreement
- * External HREC application / correspondence / approval

The attachment categories cover the most common types of documents associated with an ethics protocol. Attachments outside the pre-set category listings can be uploaded through the 'Miscellaneous' option.

Follow these steps to upload attachments:

1. Within the **Attachments** section (see Figure 8), select **Yes** or **NA** (not applicable) from the dropdown options for each attachment category.
2. For attachment categories where you have chosen **Yes**, you will need to select the add (+) sign.
3. From here, you can select '**File upload**'.

Figure 8

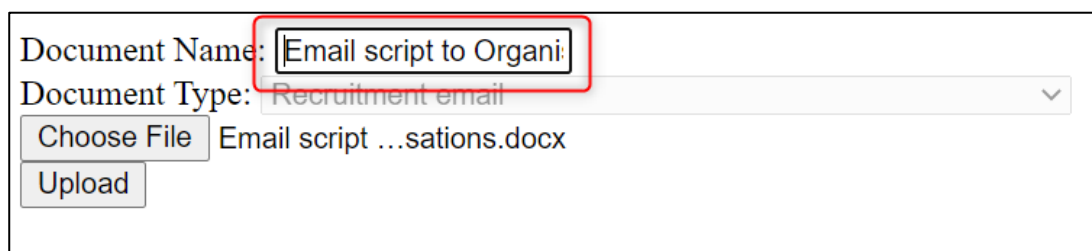


The screenshot shows the 'Attachments' section of the RIMS system. On the left is a sidebar with a list of categories: Research Methods / Techniques, Consent Process, Research Sites, Project Overview, Participant Recruitment & Activities, Analysis and Reporting, Data Management, Attachments (highlighted), and Declaration. Below the sidebar, it says 'Form: Initial Approval Submission - New Project'. To the right of the sidebar is a list of attachment categories, each with a dropdown menu and a red asterisk indicating a required field:

- NA * Social media material
- NA * Recruitment email
- NA * Letter of support
- 1 Yes * Participant Information Statement(s)
- 2 + (plus sign button)
- * File Upload (with a red 3 next to the upload icon)
- * Consent Form(s)

4. A window will appear that allows you to browse for and select the desired file. Enter an appropriate title for the file in the **Document Name** field as shown in Figure 9.

Figure 9



The screenshot shows a form with the following fields and buttons:

- Document Name: [Email script to Organi] (highlighted with a red box)
- Document Type: Recruitment email (dropdown menu)
- Choose File: Email script ...sations.docx
- Upload

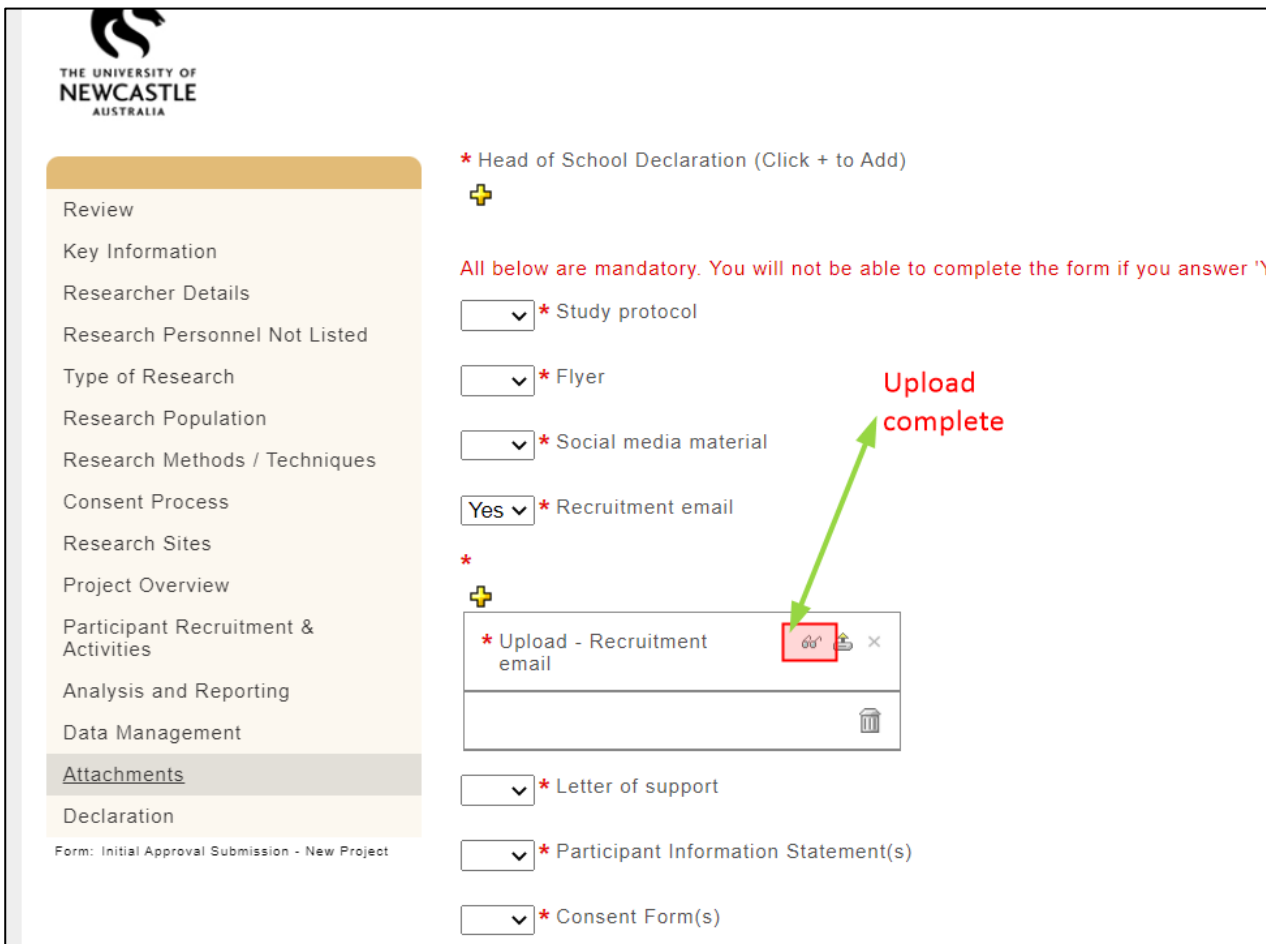
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- Once you've completed step 4, select **Upload**. After the file has uploaded, an 'eyeglasses' icon will appear as shown in Figure 10. Click on this to view your file if necessary. Please ensure this icon appears for each upload, otherwise your file may not have uploaded correctly.

Figure 10

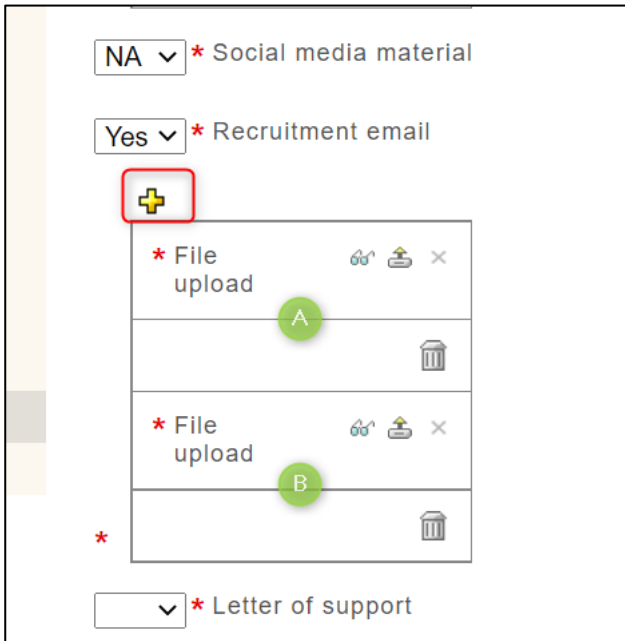


The screenshot shows the RIMS user interface for 'Initial Approval Submission - New Project'. On the left is a navigation menu with 'Attachments' selected. The main area displays a list of mandatory attachments:

- * Head of School Declaration (Click + to Add)
- All below are mandatory. You will not be able to complete the form if you answer 'N'
- * Study protocol
- * Flyer
- * Social media material
- Yes * Recruitment email
- * Upload - Recruitment email (highlighted with a red box and a green arrow pointing to it with the text 'Upload complete')
- * Letter of support
- * Participant Information Statement(s)
- * Consent Form(s)

If you need to upload multiple documents within the same attachment category, select the add (+) sign and complete steps 3 to 5 for each attachment. For example, you may need to upload 'Recruitment flyer A' and 'Recruitment flyer B'. See Figure 11 for a sample screen shot showing multiple file uploads.

Figure 11



The screenshot shows a form with several fields. At the top, there is a dropdown menu with 'NA' selected and a red asterisk, followed by the text '* Social media material'. Below this is another dropdown menu with 'Yes' selected and a red asterisk, followed by the text '* Recruitment email'. A red box highlights a plus sign icon. Below the plus sign is a section for file uploads. It contains two rows, each with a red asterisk, the text '* File upload', and icons for refresh, upload, and delete. The first row has a green circle with the letter 'A' in the center. The second row has a green circle with the letter 'B' in the center. Below the file upload section is a dropdown menu with a downward arrow and a red asterisk, followed by the text '* Letter of support'.

Please note that the file name of the attachment will not display once it has been uploaded. We acknowledge this is not ideal and have been assured by the software developer that this will be rectified during the next RIMS upgrade later in 2022.

Replacing or deleting documents

If you need to upload an updated document to your protocol (see option 1 in Figure 12), make sure any proposed changes are obvious by using the 'track changes' function or highlighting the new content in a different colour than the rest of the text in the document. This will make it easier for reviewers to see exactly what you're proposed changes are.

If you need to delete document (see option 2 in Figure 12), make sure you only delete files that are no longer relevant to your ethics protocol. If you're unsure about whether you should delete any files, [contact your College ethics advisor or the Human Research Ethics Team](#) for advice.

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Figure 12



Saving your Variation application

Once you have made all the necessary updates to your application, be sure to **Save** your data and then **Lock** the eForm.

Figure 13 shows the 'buttons' that enable you to **Save** and **Lock** the file.

Figure 13



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Submitting your application

Submit your Variation application by selecting the **Submit** button which is located at the top right corner of your eForm, as shown in Figure 14.

Figure 14

A screenshot of the RIMS eForm interface. At the top right, there is a toolbar with several buttons: a menu icon, 'Save', 'Close', 'Lock Form' (with a checked checkbox), a red 'X' icon, 'Validate', and 'Submit'. The 'Submit' button is highlighted with a red rectangular box. Below the toolbar, the form content includes a section titled 'Key Information' with a red warning message: '--- SAVE before ticking 'Lock Form' or closing the form. --- If 'Lock Form' is ticked, un-tick it to edit form.' Below this is the 'Human Research Ethics Committee' section, which includes the text 'Initial Approval Submission - New Project' and the University of Newcastle Australia logo. At the bottom, there is a section titled 'When to use this form' with explanatory text about initial submissions to the HREC.

For questions or support

If you have questions about this guide or need additional support, please contact the Human Research Ethics team on human-ethics@newcastle.edu.au.

END of document